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10/611,531	06/30/2003	Subramanian S. Venkatraman	ARC 2869 N1	2177

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,531	VENKATRAMAN ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-33 and 54-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-33 and 54-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' amendment filed 08/03/2006.

Claims 1-11, 34-53 have been previously canceled; claims 58-61 have been added.

Claims 12-33 and 54-61 are pending and included in the prosecution.

The following rejections have been overcome by virtue of applicants' amendment and remarks:

(1) The rejection of claims 12-33, 54 and 55 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

(2) The rejection of claims 12-33, and 54-57 under 35 U.S.C. 112, second paragraph, as being indefinite.

(3) The rejection of claims 12-14, 20, 22, and 54 under 35 U.S.C. 102(b) as being anticipated by US 4,840,796 ('796), this rejection is overcome by amending the claims to recite "consisting of polyurethane".

The following rejection is necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 58 and 61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection because the specification as originally field does not disclose any where or support the limitation of "polymer is solid below the process temperature" as instantly claimed by claim 58, and does not support "polyurethane polymer is a carrier polymer" as instantly claimed in claim 61. In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

The following rejections have been discussed in the previous office action and are maintained for reasons of record:

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 12, 13, 15-20, 22, 33, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by 4,638,043 ('043).

US '043 discloses a transdermal drug releasing patch that is non-toxic, non-carcinogenic and biocompatible, oxygen and water vapor permeable, flexible, and can incorporate a wide variety of drugs for a controlled, sustained release to the wearer (abstract; col.2, lines 56-57). The patch comprises support layer, i.e. backing layer (12); a polymer layer of polyurethane containing a drug (16) and a pressure sensitive adhesive layer to fix the patch to the skin (18), i.e. maintaining the patch in drug transmitting relationship with the body surface (col.2, lines 13-22; col.4, lines 45-57; figures 2 and 3). The drug is contained in an amount of 1-10% in the polyurethane layer and includes analgesics (col.2, line 31; col.3, lines 59-60). The drug and a material that aids in the transport of the drug into the skin, i.e. permeation enhancer, are blended into the polyurethane layer (col.4, lines 1-7). The drug containing layer is made of polyurethane comprises the reaction product of dicyclohexyl methane diisocyanate, polytetramethylene ether polyol, and 1,4-butane diol which is TECOFLEX^{R} (col.8, lines 56-65). The polyurethane polymer is liquid at room temperature to facilitate admixture of drug to form a homogenous blend, and this implies that the melt temperature of the polyurethane is below 100^{0} C and the drug can be blended into the polymer at this temperature (col.2, lines 42-46). The polyurethane polymer does not contain any solvents (col.3, lines 32-33). The modulus of the melt-blended mixture claimed in claim 33 is inherent to specific polymer and specific drug.

Response to Arguments

5. Applicant's arguments filed 08/03/2006 have been fully considered but they are not persuasive. Applicants traverse this rejection by arguing that:

- Szycher mixes pre-cured pre-polymeric liquid at room temperature and not the polymerized polymer and the drug is incorporated in the material before the material is cured. Curing changes the thermal and mechanical property of material and any person skilled in the art will know that such cured polymers cannot be melt-blended.

In response to this argument, applicants' attention is drawn to the scope of the present claims that are directed to transdermal drug delivery device, and the drug-containing layer consisting of polyurethane that has process temperature less than 150^0 C. Szycher disclosed transdermal drug delivery system comprising a layer of polyurethane comprising a drug. The process temperature of polyurethane is inherent. Mixing the drug in the polyurethane layer before or after the curing is directed to method of production of the device, and does not impart patentability to the claims directed to product. The instant end product is not materially different from the product of the prior art. The burden is on applicants to show that blending the polymer with the drug after curing the polymer will provide a product materially different from the blending the polymer with the drug before curing. The reference disclosed the polyurethane made from the same elements as instantly claimed.

- Applicants argue that TECOFLEX disclosed by Szycher is NOT on the drug-containing layer 16, but rather it is about the substrate 12 (see column 4 line 55 to column 5 line 15), which supports the drug-containing layer 16.

In response to this argument, applicants' attention is drawn to the teaching of Szycher on col.6, lines 20-23, where the reference disclosed that the materials used to make the drug containing layers is the same as the materials used to make the substrate but without the drug. Therefore, TECOFLEX can be used for both the drug containing layer and the substrate.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 12-20, 22, 33, 54 and 58-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,638,043 ('043).

US '043 teaches a transdermal drug releasing patch that is non-toxic, non-carcinogenic and biocompatible, oxygen and water vapor permeable, flexible, and can incorporate a wide variety of drugs for a controlled, sustained release to the wearer (abstract; col.2, lines 56-57). The patch comprises support layer, i.e. backing layer (12); a polymer layer of polyurethane containing a drug (16) and a pressure sensitive adhesive layer to fix the patch to the skin (18), i.e. maintaining the patch in drug transmitting relationship with the body surface (col.2, lines 13-22; col.4, lines 45-57; figures 2 and 3). The drug is contained in an amount of 1-10% in the polyurethane layer and includes analgesics (col.2, line 31; col.3, lines 59-60). The drug and a material that aids in the transport of the drug into the skin, i.e. permeation enhancer, are blended into the polyurethane layer (col.4, lines 1-7). The drug containing layer is made of polyurethane comprises the reaction product of dicyclohexyl methane diisocyanate, polytetramethylene ether polyol, and 1,4-butane diol (col.8, lines 56-65). The polyurethane polymer is liquid at room temperature to facilitate admixture of drug to form a homogenous blend, i.e. below 100^0 C (col.2, lines 42-46). The polyurethane polymer does not contain any solvents that may hinder the effectiveness of many drugs (col.3, lines 32-33).

However, US '043 does not explicitly teach that the process temperature and the modulus of the polyurethane polymer. The process temperature and the modulus of the polyurethane polymer disclosed by US '043 are expected to be the same as instantly claimed because the reference teaches the same polymer formed from the same polymer reaction that is liquid at room temperature, i.e. below 100^0 C but does not specify temperature between 40^0 C and 90^0 C.

The temperature between 40^0 C and 90^0 C does not impart patentability to the claims absent evidence to the contrary.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery patch comprising a polyurethane polymer layer containing a drug wherein the polyurethane layer is liquid at room temperature and contains no solvents as disclosed by US '043, and adjust the temperature to that required to melt the drug into the liquid polyurethane polymer according to specific drug used without the use of any solvents, motivated by the teaching of US '043 that the absence of solvent is advantageous because solvents hinder the effectiveness of many drugs, with reasonable expectation of having transdermal drug delivery patch containing polyurethane polymer layer that is non-toxic and biocompatible produced without using any solvents at a temperature below 100^0 C, thus, reserving the drug effectiveness and providing the maximum desired effect to the patient.

Response to Arguments

9. Applicant's arguments filed 08/03/2006 have been fully considered but they are not persuasive. Applicants repeat the same argument above and further argue that not all the polyurethanes are the same.

In response, the examiner repeat the same response as in section 5 above, and further submits that the reference suggested that both drug containing layer and the substrate layer can be made from the same polyurethane (col.6, lines 20-23).

10. Claims 12-33, 54-61 rejected under 35 U.S.C. 103(a) as being unpatentable over US '043 in view of US 5,273,757 ('757) or *vise versa*.

The teachings of US '043 are discussed above. US '043 does explicitly teach that the process temperature and the modulus of the polyurethane polymer. US '043 does not teach specific drugs and permeation enhancer and the amounts of all the ingredients. US '043 does not teach the acrylate adhesive in skin contact layer.

The specific drugs and enhancers as well as amounts of different ingredients do not impart patentability to the claims, absent evidence to the contrary.

The acrylate adhesive is known as skin contact layer, its instant use does not impart patentability to the claims, absent evidence to the contrary.

US '757 teaches transdermal drug delivery device suitable to deliver drug to the skin comprises backing layer, and hot melt adhesive layer comprising 10-100% polyurethane adhesive, 10-80% plasticizer such as fatty acid esters, and drug such as fentanyl (abstract; col.col.3, lines 25-30, 54; col.4, lines 6-9, 39-43). The hot melt adhesive layer has process temperature between 40^0 C and 80^0 C and does not contain

any solvent therefore the process is advantageous manner for less temperature-sensitive substances because no toxic solvent residues can remain in the transdermal patch, less time consuming, less environmental polluting, and coast saving (col.2, lines 54-61; col.4, lines 43-54).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device that has matrix formed of melt blend of polyurethane, active agent and permeation enhancer as disclosed by US '043, and use a temperature process between 40^0 C and 80^0 C and fentanyl as an active agent, and fatty acid ester as an enhancer as disclosed by US '757, motivated by the teaching of US '757 that process temperature between 40^0 C and 80^0 C without solvent is advantageous manner for less temperature-sensitive substances because no toxic solvent residues can remain in the transdermal patch, less time consuming, less environmental polluting, and coast saving, with reasonable expectation of having transdermal drug delivery device that has matrix comprising melt blend of polyurethane, fentanyl, and fatty acid ester that is processed at 40^0 C and 80^0 C without solvent that is advantageously prepared in a manner suitable for less temperature-sensitive substances, not toxic, less time consuming, less environmental polluting, and coast saving, and meanwhile deliver fentanyl effectively in enhanced manner to the skin of the patient in need of such treatment.

Vise versa, US '757 does not teach the skin contact layer of the transdermal device or the specific starting material for the polyurethane.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal device to deliver fentanyl comprising matrix of polyurethane having a process temperature between 40^0 C and 80^0 C without solvent as disclosed by US '757, and add the skin contact layer to protect the matrix as disclosed by US '043, and replace the polyurethane by the polyurethane produced by the reaction product of dicyclohexyl methane diisocyanate, polytetramethylene ether polyol, and 1,4-butane diol as disclosed by US '043, motivated by the teaching of US '043 that such polyurethane is non-toxic, non-carcinogenic and biocompatible, oxygen and water vapor permeable, flexible, and provides a controlled, sustained release of the drug to the wearer, with reasonable expectation of having a matrix comprising fentanyl, fatty acid enhancer, and polyurethane produces by the reaction product of dicyclohexyl methane diisocyanate, polytetramethylene ether polyol, and 1,4-butane diol that is non-toxic, non-carcinogenic and biocompatible, oxygen and water vapor permeable and flexible that provides controlled, sustained release of fentanyl to the wearer.

Response to Arguments

11. Applicant's arguments filed 08/03/2006 have been fully considered but they are not persuasive. Applicants argue that US '757 has processing temperature between 40^0 C and 80^0 C is due to the pressure sensitive adhesive composition as a whole, and not due to the polyurethane by itself.

In response to this argument, applicants' attention is drawn to the scope of the present claims that are directed to transdermal drug delivery device, and the drug-

containing layer consisting of polyurethane that has process temperature less than 150^0 C. Szycher disclosed transdermal drug delivery system comprising a layer of polyurethane comprising a drug. Jaeger disclosed transdermal drug delivery device comprising adhesive layer comprising polyurethane and also disclosed making the adhesive layer by melt blending at temperature of 40^0 C and 80^0 C. The process temperature is directed to the method of making and not a product. Jaeger recognized making the adhesive layer containing the drug by melting the adhesive and the drug at a temperature that is safe and advantageous to heat sensitive drugs that ranges from 40^0 C and 80^0 C. One having ordinary skill in the art at the time of the invention would have benefit from the teaching of Jaeger to melt the adhesive and the other ingredient without solvent using the minimal suitable temperature because this process is advantageous manner for temperature-sensitive substances, and no toxic solvent residues can remain in the transdermal patch, less time consuming, less environmental polluting, and coast saving.

12. Claims 21, 28, 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '043 in view of US '757 and further in view of US '6,139,866 ('866).

The combined teachings of US '043 and US '757 are discussed above.

The combination of US '043 with any of US '757 does not specifically teach the glycerol monolaurate permeation enhancer, or acrylate adhesive as skin contact layer.

US '866 teaches percutaneous formulation to deliver fentanyl wherein the formulation is stable and has little irritation to the skin and excellent in percutaneous permeation of fentanyl (abstract). The formulation comprises 0.05-20% of fentanyl, 0.1-98% of pressure sensitive adhesive that can be acrylate adhesive, and 0.01-20% of permeation enhancer such as glycerol monolaurate which has recognized absorption enhancing effect on the skin (col.1, lines 65-67; col.2, lines 1-2, 67; col.4, lines 9-11, 28-31, 37-39).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device that has matrix formed of melt blend of polyurethane, fentanyl and fatty acid permeation enhancer as disclosed by US '043 combined with US '757, and replace the permeation enhancer by glycerol monolaurate and further use acrylate as skin contact adhesive as disclosed by US '866, motivated by the teaching of US '866 such a percutaneous formulation comprising glycerol monolaurate and acrylate adhesive delivers fentanyl with little irritation to the skin and provides excellent recognized percutaneous permeation, with reasonable expectation of having a transdermal melt blend matrix comprising polyurethane, fentanyl and glycerol monolaurate and acrylate skin contact layer wherein the device has excellent permeation to fentanyl without skin irritation.

Response to Arguments

13. Applicant's arguments filed 08/03/2006 have been fully considered but they are not persuasive. Applicants argue that Chono does not teach polyurethane and teaches

the adhesive layer containing the drug is made with solvent, and this is irrelevant to the melt blending of the present invention.

In response to this argument, it is argued that Chono is relied upon for the solely teaching of glycerol monolaurate permeation enhancer and acrylate adhesive as skin contact layer. Polyurethane is taught by the Szycher, and one having ordinary skill in the art would have been replaced the permeation enhancer taught by Szycher by glycerol monolaurate taught by Chono, and further use acrylate as skin contact adhesive as disclosed by Chono, motivated by the teaching of Chono that such a percutaneous formulation comprising glycerol monolaurate and acrylate contact adhesive delivers fentanyl with little irritation to the skin and provides excellent recognized percutaneous permeation, with reasonable expectation of having a transdermal melt blend matrix comprising polyurethane, fentanyl and glycerol monolaurate and acrylate adhesive skin contact layer wherein the device has excellent permeation to fentanyl without skin irritation. Chono is an analogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Chono is from the field f applicants' endeavor, and one having ordinary skill in the art seeking for permeation enhancer for fentanyl and skin contact adhesive layer would have definitely looked at Chono's disclosure that delivers fentanyl transdermally.

14. Claims 21, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '043 in view of US '757, and further in view of US 5,066,648 ('648).

The combined teachings of US '043 and US '757 are discussed above.

The combination of US '043 with US '757 does not specifically teach lauryl pyroglutamate as a permeation enhancer.

US '648 teaches pryoglutamic acid esters as safe dermal permeation enhancers being capable of improving delivery of active agent through the skin and into the general circulation and undergo fast metabolic breakdown into non-toxic metabolic products as soon as they reach the live area of the skin (abstract; col.3, lines 25-42).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device that has matrix comprising melt blend of polyurethane, fentanyl and permeation enhancer as disclosed by US '043 in combination with US '757, and replace the enhancer by pyroglutamic acid esters as disclosed by US '648, motivated by the teaching of US '648 that pryoglutamic acid esters are safe dermal permeation enhancers capable of improving delivery of active agent through the skin and into the general circulation and undergo fast metabolic breakdown into non-toxic metabolic products as soon as they reach the live area of the skin, with reasonable expectation of having a transdermal device that deliver fentanyl from a melt blend matrix comprising polyurethane and lauryl pyroglutamate with improved permeation of fentanyl to the circulation without causing any toxic effects.

Response to Arguments

15. Applicant's arguments filed 08/03/2006 have been fully considered but they are not persuasive. Applicants argue that anybody skilled in the art knows that permeation enhancers do not function the same way for different drugs in different matrixes. Alexander does not mention fentanyl, and does not mention polyurethane as the drug layer carrier polymer or melt-blending.

In response to this argument, it is argued that Alexander teaches that pryoglutamic acid esters are useful to deliver analgesics and sedatives (col.5, lines 52, 56). The reference teaches that pryoglutamic acid esters enhance skin permeation of the therapeutic agent (col.4, lines 45-46). Hence permeation enhancers do not react with the drug or the matrix materials. Enhancers act as skin softener to soften the stratum corneum of the skin that acts as a barrier. The amount of the enhancers used is the parameters that is affected by the kind of the drug and the adhesive, and not enhancer itself. Pryoglutamic acid esters will enhance the delivery of any drug and its amount depends on the solubility, hydrophilicity and lipophilicity of the drug that control the transport of the drug across the stratum corneum.

16. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '043 in view of US '757, and further in view of US 5,599,648 ('289).

The combined teachings of US '043 and US '757 are discussed above.

The combination of US '043 with any of US '757 does not specifically teach the skin contact adhesive as acrylate adhesive.

US '289 teaches wound dressing comprising skin contact acrylate adhesive layer that is preferred because it is hypoallergenic and non-irritating to the skin (col.5, lines 35-39, 45-49).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal drug delivery device that has matrix formed of melt blend of polyurethane and fentanyl, and skin contact layer as disclosed by US '043 in combination with US '757, and use acrylate adhesive to form the skin contact layer as disclosed by US '289, motivated by the teaching of US '289 that acrylate adhesive layer is preferred because it is hypoallergenic and non-irritating to the skin, with reasonable expectation of having transdermal drug delivery device that has matrix formed of melt blend of polyurethane and fentanyl, and comprising an acrylate adhesive skin contact layer that can be worn by the patient without causing irritation or allergic reaction, thus, delivers the active agent comfortably to the user.

Response to Arguments

17. Applicant's arguments filed 08/03/2006 have been fully considered but they are not persuasive. Applicants argue that Castellana teaches wound dressing comprising skin contact acrylate adhesive layer and therefore one would make the presently claimed invention from the teaching of Castellana.

In response, it is argued that Castellana reference is relied upon for the solely teaching of skin contact acrylate adhesive. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent

to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Castellana is from the field f applicants' endeavor, and one having ordinary skill in the art would have used acrylate adhesive in the skin contact layer of transdermal device motivated by the teaching of Castellana that acrylate adhesive layer is preferred because it is hypoallergenic and non-irritating to the skin, with reasonable expectation of having transdermal drug delivery device that has matrix formed of melt blend of polyurethane and fentanyl, and comprising an acrylate adhesive skin contact layer that can be worn by the patient without causing irritation or allergic reaction, thus, delivers the active agent comfortably to the user.

Conclusion

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

IG

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600